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09/854,039	05/11/2001	James P. Blasingame	0720.P001A	8173

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EXAMINER
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TOMASZEWSKI, MICHAEL

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/854,039	Applicant(s) BLASINGAME ET AL.	
	Examiner Mike Tomaszewski	Art Unit 3626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 33-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 33-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____.  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Notice To Applicant***

1. This communication is in response to the application filed on 7/17/2006. Claims 1-32 have been cancelled. Claims 33-56 are newly added and are pending.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 34, 36-41, 43-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) Dependent claims 34, 36-41, and 43-44 are unclear and indefinite because they depend from cancelled claim 1. Similarly, claim 42 is unclear and indefinite because it depends from dependent claim 41. Examiner will proceed with the examination process

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assuming that these dependencies are erroneous and Applicant intended dependent claims 34, 36-41, and 43-44 to depend from independent claim 33.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 33-39 and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joao (6,283,761; hereinafter Joao), in view of Campbell et al. (6,047,259; hereinafter Campbell).

(A) As per new claim 33, Joao discloses a networked medical information system for clinical practices which facilitates the exchange of medical data between doctor and patient, and enables the generation of an editable physician's preliminary chart note, comprising:

- (1) a central server containing medical information databases thereon (Joao: col. 2, lines 63-65);

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- (2) one or more client computers, including patient's computers, physician's computers and physician's front office administrative computers, all able to link to said central server using standard shared communications protocols (Joao: col. 15, lines 46-53);
- (3) a pre-visit summary text database used to generate a pre-visit patient summary including condition-specific information derived from said patient answers to said condition-specific questions (Joao: col. 1, lines 46-62; col. 20, lines 21-27; col. 26, lines 10-38);
- (4) a physician oriented condition-specific database, used to generate condition-specific material for the purpose of preparing a pre-visit physician report based upon said patients answers (Joao: col. 20, lines 21-27; col. 26, lines 10-38);
- (5) a medical chart note database used to build an editable preliminary medical chart note including condition-specific clinical information for the physician (Joao: col. 19, lines 65-col. 20, line 8); and
- (6) a medical education database used to generate a condition-specific post-visit report for the patient (Joao: col. 17, lines 25-60; col. 25, lines 54-58; col. 26, lines 10-38).

Joao, however, fails to *expressly* disclose a networked medical information system for clinical practices which facilitates the exchange of medical data between

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doctor and patient, and enables the generation of an editable physician's preliminary chart note, comprising:

- (7) a database of patient oriented structured condition-specific interviews having a series of condition-specific questions, accessible by said patient's computers, whereby patients answer said condition-specific questions using patients computer, prior to a doctors office visit (Campbell: abstract; col. 13, lines 10-18; Fig. 3-14).

Nevertheless, these features are old and well known in the art, as evidenced by Campbell. In particular, Campbell discloses a networked medical information system for clinical practices which facilitates the exchange of medical data between doctor and patient, and enables the generation of an editable physician's preliminary chart note, comprising:

- (7) a database of patient oriented structured condition-specific interviews having a series of condition-specific questions, accessible by said patient's computers, whereby patients answer said condition-specific questions using patients computer, prior to a doctors office visit (Campbell: abstract; col. 13, lines 10-18; Fig. 3-14).

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One of ordinary skill would have found it obvious at the time of the invention to combine the teachings of Campbell with the teachings of Joao with the motivation of managing a medical practice (Campbell: col. 1, lines 50-61).

(B) As per new claim 34, Joao fails to *expressly* disclose the networked medical information system for clinical practices which facilitates the exchange of medical data between doctor and patient, and enables the generation of an editable physician's preliminary chart note according to claim 1, wherein said database of patient oriented structured condition-specific interviews having a series of condition-specific questions, accessible by said patient's computers, whereby patients answer said questions using patients computer, prior to a doctors office visit, *further includes an interactive branching capability for the purpose of adjusting condition-specific questions based upon answers to previous questions within the database.*

Nevertheless, these features are old and well known in the art, as evidenced by Campbell. In particular, Campbell discloses the networked medical information system for clinical practices which facilitates the exchange of medical data between doctor and patient, and enables the generation of an editable physician's preliminary chart note according to claim 1, wherein said database of patient oriented structured condition-specific interviews having a series of condition-specific questions, *further includes an interactive branching capability for the purpose of adjusting condition-specific questions based upon answers to previous questions within the database* (Campbell: abstract).

One of ordinary skill would have found it obvious at the time of the invention to combine the teachings of Campbell with the teachings of Joao with the motivation of managing a medical practice (Campbell: col. 1, lines 50-61).

(C) As per new claim 35, Joao fails to *expressly* disclose the networked medical information system for clinical practices which facilitates the exchange of medical data between doctor and patient, and enables the generation of an editable physician's preliminary chart note according to claim 34, wherein said interactive capability for the purpose of adjusting condition-specific questions based upon answers to previous questions within the database, *enables adjustment of questions based upon age and gender of a patient answering said adjusted condition-specific questions*.

Nevertheless, these features are old and well known in the art, as evidenced by Campbell. In particular, Campbell discloses the networked medical information system for clinical practices which facilitates the exchange of medical data between doctor and patient, and enables the generation of an editable physician's preliminary chart note according to claim 34, wherein said interactive capability for the purpose of adjusting condition-specific questions based upon answers to previous questions within the database, *enables adjustment of questions based upon age and gender of a patient answering said adjusted condition-specific questions* (Campbell: abstract; col. 9, lines 56-64).



One of ordinary skill would have found it obvious at the time of the invention to combine the teachings of Campbell with the teachings of Joao with the motivation of managing a medical practice (Campbell: col. 1, lines 50-61).

(D) As per new claim 36 Joao discloses the networked medical information system for clinical practices which facilitates the exchange of medical data between doctor and patient, and enables the generation of an editable physician's preliminary chart note according to claim 1, wherein said pre-visit summary text database used to generate a pre-visit patient summary including condition-specific information derived from said patient answers to said condition-specific questions, *further generates information related to patient's condition and transmits said information to the patient* (Joao: col. 14, line 59-col. 15, line 18).

(E) As per new claim 37, Joao discloses the networked medical information system for clinical practices which facilitates the exchange of medical data between doctor and patient, and enables the generation of an editable physician's preliminary chart note according to claim 1, wherein said pre-visit summary text database used to generate a pre-visit patient summary including condition-specific information derived from said patient answers to said condition-specific questions, *further generates key questions relating to patient's condition, for the patient to ask the physician during the office visit* (Joao: col. 1, lines 46-62; col. 19, lines 54-64).

Joao, however, fails to *expressly* disclose the networked medical information system for clinical practices which facilitates the exchange of medical data between doctor and patient, and enables the generation of an editable physician's preliminary chart note according to claim 1, wherein said pre-visit summary text database used to generate a pre-visit patient summary including condition-specific information derived from said patient answers to said condition-specific questions, further generates *condition-specific* key questions relating to patient's condition.

Nevertheless, these features are old and well known in the art, as evidenced by Campbell. In particular, Campbell discloses the networked medical information system for clinical practices which facilitates the exchange of medical data between doctor and patient, and enables the generation of an editable physician's preliminary chart note according to claim 1, wherein said pre-visit summary text database used to generate a pre-visit patient summary including condition-specific information derived from said patient answers to said condition-specific questions, further generates *condition-specific* key questions relating to patient's condition (Campbell: abstract; col. 13, lines 10-18; Fig. 3-14).

One of ordinary skill would have found it obvious at the time of the invention to combine the teachings of Campbell with the teachings of Joao with the motivation of managing a medical practice (Campbell: col. 1, lines 50-61).

(F) As per new claim 38, Joao discloses the networked medical information system for clinical practices which facilitates the exchange of medical data between doctor and

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patient, and enables the generation of an editable physician's preliminary chart note according to claim 1, wherein said physician oriented condition-specific database, used to generate condition-specific material for the purpose of preparing a pre-visit physician report based upon said patients answers, *further generates expert medical information relating to patients condition for the physician, and transmits said expert medical information to the physician* (Joao: col. 14, line 59-col. 15, line 18; col. 20, lines 21-27).

(G) As per new claim 39, Joao discloses the networked medical information system for clinical practices which facilitates the exchange of medical data between doctor and patient, and enables the generation of an editable physician's preliminary chart note according to claim 1, wherein said physician oriented condition-specific database, used to generate condition-specific material for the purpose of preparing a pre-visit physician report based upon said patients answers, *further generates information relating to patients condition including a differential diagnosis, work-up algorithms, treatment considerations and literature references, and transmits this information to the physician* (Joao: col. 14, line 59-col. 15, line 18; col. 20, lines 21-27).

(H) As per new claim 41, Joao discloses the networked medical information system for clinical practices which facilitates the exchange of medical data between doctor and patient, and enables the generation of an editable physician's preliminary chart note according to claim 1, wherein said medical chart note database used to build an editable preliminary medical chart note including condition-specific clinical information

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for the physician, is *further used to generate a complete final chart note* (Joao: col. 19, lines 65-col. 20, line 8).

(I) As per new claim 42, Joao discloses the networked medical information system for clinical practices which facilitates the exchange of medical data between doctor and patient, and enables the generation of an editable physician's preliminary chart note according to claim 41, *wherein said complete final chart note is sent to patients file for the purpose of updating patients file* (Joao: col. 19, lines 65-col. 20, line 8).

(J) As per new claim 43, Joao discloses the networked medical information system for clinical practices which facilitates the exchange of medical data between doctor and patient, and enables the generation of an editable physician's preliminary chart note according to claim 1, wherein said medical education database used to generate a condition-specific post-visit report for the patient, *further enables physician to select condition-specific medical educational materials and transmit said materials to the patient* (Joao: col. 17, lines 25-60; col. 4, lines 48-58).

(K) As per new claim 44, Joao discloses the networked medical information system for clinical practices which facilitates the exchange of medical data between doctor and patient, and enables the generation of an editable physician's preliminary chart note according to claim 1, wherein said medical education database used to generate a condition-specific post-visit report for the patient, *further generates expert medical*

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*information relating to patients condition for the purpose of educating the physician after the office visit* (Joao: col. 17, lines 25-60; col. 4, lines 48-58).

(L) Claims 45-51 and 53-56 substantially repeat the same limitations of claims 33-39 and 41-44 and therefore, are rejected for the same reasons given for those claims and incorporated herein.

6. Claims 40 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Joao, in view of Campbell, as applied to claim 33 and 45 above, and further in view of Segal (6,754,655; hereinafter Segal).

(A) As per new claim 40, Joao discloses the networked medical information system for clinical practices which facilitates the exchange of medical data between doctor and patient, and enables the generation of an editable physician's preliminary chart note according to claim 1, wherein said physician oriented condition-specific database, used to generate condition-specific material for the purpose of preparing a pre-visit physician report based upon said patients answers, *further generates key questions for the patient to ask the physician, and transmits said key questions to the physician along with a rationale for asking each of said key questions, for the purpose of preparing and educating the physician prior to the office visit* (Joao: col. 1, lines 46-62; col. 19, lines 54-64).

Joao, however, fails to *expressly* disclose the networked medical information system for clinical practices which facilitates the exchange of medical data between doctor and patient, and enables the generation of an editable physician's preliminary chart note according to claim 1, wherein said physician oriented condition-specific database, used to generate condition-specific material for the purpose of preparing a pre-visit physician report based upon said patients answers, *further transmits a rationale for asking each of said key questions, for the purpose of preparing and educating the physician prior to the office visit.*

Nevertheless, these features are old and well known in the art, as evidenced by Segal. In particular, Segal discloses the networked medical information system for clinical practices which facilitates the exchange of medical data between doctor and patient, and enables the generation of an editable physician's preliminary chart note according to claim 1, wherein said physician oriented condition-specific database, used to generate condition-specific material for the purpose of preparing a pre-visit physician report based upon said patients answers, *further transmits a rationale for asking each of said key questions, for the purpose of preparing and educating the physician prior to the office visit* (Segal: col. 12, lines 15-24; Examiner considers diagnostic/medical tests to include a question or series of questions that are used to query a patient for the purpose of ascertaining their medical condition.).

One of ordinary skill would have found it obvious at the time of the invention to combine the teachings of Segal within the teachings of Joao with the motivation of

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providing a means of learning about a certain healthcare topic (Joao: col. 7, lines 10-15) and evaluating the usefulness of a particular finding (Segal: col. 2, lines 29-30).

(B) Claim 52 substantially repeats the same limitations of claim 40 and therefore, is rejected for the same reasons given for claim 40 and incorporated herein.

### ***Response to Arguments***

7. Applicant's arguments filed 7/17/06 have been fully considered but are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 7/17/06.

(A) On pages 12-13 of the 7/17/06 response, Applicant argues that none of the prior art references previously cited (alone or in combination) disclose, teach or claim a combination of the Applicant's claimed databases, and the claimed system or method which acts to coordinate each database in order to produce the work product of the system, namely patient and physician oriented reports and education. Applicant further argues that none of the prior art references even remotely suggest using a database system for creating an editable chart note for a practicing physician in order to aid in rendering services within a clinical practice setting.

In response, Examiner respectfully submits that the prior art references applied do indeed teach and suggest Applicant's claimed invention, as discussed in sections 4-6, *supra*.

(B) On page 13 of the 7/17/06 response, Applicant argues that there is a "long felt need for this type of system and method approach."

In response, Examiner notes that establishing long-felt need requires objective evidence that an art recognized problem existed in the art for a long period of time without solution. The relevance of long-felt need and the failure of others to the issue of obviousness depends on several factors.

First, the need must have been a persistent one that was recognized by those of ordinary skill in the art. *In re Gershon*, 372 F.2d 535, 539, 152 USPQ 602, 605 (CCPA 1967) ("Since the alleged problem in this case was first recognized by appellants, and others apparently have not yet become aware of its existence, it goes without saying that there could not possibly be any evidence of either a long felt need in the . . . art for a solution to a problem of dubious existence or failure of others skilled in the art who unsuccessfully attempted to solve a problem of which they were not aware."); *Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 217 USPQ 1281 (Fed. Cir. 1983) (Although the claimed invention achieved the desirable result of reducing inventories, there was no evidence of any prior unsuccessful attempts to do so.).



Second, the long-felt need must not have been satisfied by another before the invention by applicant. *Newell Companies v. Kenney Mfg. Co.*, 864 F.2d 757, 768, 9 USPQ2d 1417, 1426 (Fed. Cir. 1988) (Although at one time there was a long-felt need for a “do-it-yourself” window shade material which was adjustable without the use of tools, a prior art product fulfilled the need by using a scored plastic material which could be torn. “[O]nce another supplied the key element, there was no long-felt need or, indeed, a problem to be solved”).

Third, the invention must in fact satisfy the long-felt need. *In re Cavanagh*, 436 F.2d 491, 168 USPQ 466 (CCPA 1971).

Fourth, other factors contributing to the presence of a long-felt need must be considered. For example, the failure to solve a long-felt need may be due to factors such as lack of interest or lack of appreciation of an invention’s potential or marketability rather than want of technical know-how. *Scully Signal Co. v. Electronics Corp. of America*, 570 F.2d 355, 196 USPQ 657 (1st. Cir. 1977). See also *Environmental Designs, Ltd. v. Union Oil Co. of Cal.*, 713 F.2d 693, 698, 218 USPQ 865, 869 (Fed. Cir. 1983) (presence of legislative regulations for controlling sulfur dioxide emissions did not militate against existence of long-felt need to reduce the sulfur content in the air); *In re Tiffin*, 443 F.2d 344, 170 USPQ 88 (CCPA 1971) (fact that affidavit supporting contention of fulfillment of a long-felt need was sworn by a licensee adds to the weight to be accorded the affidavit, as long as there is a bona fide licensing agreement entered into at arm’s length).

Fifth, the arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, **solution of a long-felt need**, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.

### ***Conclusion***

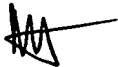
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mike Tomaszewski whose telephone number is (571)272-8117. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571)272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MT



C. LUKE GILLIGAN  
PATENT EXAMINER